

## REMARKS

Applicants' attorney spoke with the Examiner via telephone conference on June 2, 2004, and thanks the Examiner for her time and courtesy during that interview. The contents of a draft of this amendment were discussed. The Examiner indicated that the previously-cited art did not read on the claims of this Amendment, which reflects changes made during the interview.

### Double Patenting

An executed terminal disclaimer is attached with respect to co-pending and commonly-owned U.S. Patent Application Serial No. 09/924,556. As a result, Applicants request withdrawal of the provisional double patenting rejection as to claims 36-42 and 56-67.

### 35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

### Claims 36-42

Claim 36 has been amended to more positively recite the anastomosis device, claiming "[a]n anastomosis system for connecting a graft vessel to a target vessel, the tool comprising a one-piece anastomosis device having a diameter; a first tube configured to receive said anastomosis device; a second tube concentric with the first tube, the first and second tube movable with respect to one another to deploy the anastomosis device, wherein

the diameter of said anastomosis device increases upon deployment; and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out of the side of the tube.”

In contrast, U.S. Pat. No. 5,833,698 to Hinchliffe et. al. (“Hinchliffe”) neither discloses nor suggests every element of amended claim 36. Instead, Hinchliffe discloses an anastomosis device that decreases in diameter upon deployment. (e.g., figures 25-28; column 11, lines 46-50). In addition, U.S. Pat. No. 6,024,748 to Manzo (“Manzo”) neither discloses nor suggests every element of amended claim 36. Instead, Manzo discloses a plurality of individual clips rather than a “one-piece anastomosis device.” (e.g., Figures 8-9; column 3, line 3; column 6, lines 12-15; column 9, lines 43-48; column 11, lines 13-16).

Thus, neither cited reference neither expressly nor inherently describes each and every element claimed in amended claim 36, and Applicants believe claim 36 is in condition for allowance. Claims 37-42 depend directly or indirectly from claim 36, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 56-59

Claim 56 has been amended to claim “[a]n anastomosis tool for use in connecting an end of a graft vessel to the side of a target vessel, the tool including a vessel penetrating member without a passage therethrough, said vessel penetrating member configured to penetrate the target vessel, wherein the tool is configured to penetrate the target vessel and deliver a one-piece anastomosis device to connect the graft vessel and the target vessel.”

In contrast, U.S. Pat. No. 5,976,178 to Goldsteen et. al. (“Goldsteen”) neither expressly nor inherently describes every element of amended claim 56. Rather, Goldsteen discloses a vessel penetrating member having a passage therethrough to receive a guidewire. (e.g., column 12, lines 12-15; column 16, lines 37-41; column 17, line 65 through column 18,

line 2; Figures 15-15g; 18-20; 33-38). Thus, Goldsteen neither expressly nor inherently describes a vessel penetrating member without a passage therethrough.

Goldsteen neither expressly nor inherently describes each and every element claimed in amended claim 56, and Applicants believe claim 56 is in condition for allowance. Claims 57-59 depend directly or indirectly from claim 56, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 60-64

Claim 60 has been amended to claim a method comprising “receiving an anastomosis device on an anastomosis device applicator having a substantially rigid vessel penetrating member; connecting a graft vessel to the anastomosis device on the anastomosis device applicator; penetrating a target vessel with the vessel penetrating member of the anastomosis device applicator; advancing the anastomosis device into the penetration in the target vessel; deploying the anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel; and maintaining the anastomosis device applicator and vessel penetrating member outside of the lumen of the graft vessel during the receiving, connecting, penetrating, advancing and deploying.”

In contrast, Goldsteen neither expressly nor inherently describes every element of amended claim 56. Rather, Goldsteen discloses placing a vessel penetrating member and anastomosis device applicator inside the lumen of the graft. (*e.g.*, column 12, lines 27-57; column 17, line 65 through column 18, line 2; Figures 15-15g; 18-20). Thus, Goldsteen neither expressly nor inherently describes maintaining the anastomosis device applicator and vessel penetrating member outside of the lumen of the graft vessel during the receiving, connecting, penetrating, advancing and deploying.

Thus, Goldsteen neither discloses nor suggests each and every element claimed in amended claim 60, and Applicants believe claim 60 is in condition for allowance. Claims 61-64 depend directly or indirectly from claim 60, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 65-67

Claim 65 has been amended to recite the anastomosis device more positively, claiming “providing a one-piece anastomosis device; receiving said anastomosis device on an anastomosis device applicator including a first tube and a second tube; connecting a graft vessel to said anastomosis device on the anastomosis device applicator with an end of the graft vessel passing out a side hole of at least one of the first and second tubes; and deploying said anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel.”

The same discussion of Manzo applies here as applied in the discussion of claims 36-42 above. Thus, Manzo neither expressly nor inherently describes each and every element claimed in amended claim 65, and Applicants believe claim 60 is in condition for allowance. Claims 66-67 depend directly or indirectly from claim 65, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar  
Attorney for Applicants  
Reg. No. 45,076  
Tel. No. (650) 331-7162  
Chief Patent Counsel  
Cardica, Inc.